

REMARKS

I. Status of the Claims

With entry of this amendment, claims 58-73 are pending. Claims 46-53 were previously cancelled. Applicant cancels claims 1-45, and 54-57 without surrender or disclaimer of the subject matter recited therein. These claims were previously withdrawn following a restriction requirement, and Applicant reserves the right to file divisional applications directed to the subject matter of those claims.

Applicant has amended claims 58, 60, 63, 68, and 69 by deleting "adherence" and inserting "adhesion to endothelial cells." Support for this amendment can be found in the specification on page 1, lines 17-18. Applicant has also amended claims 58 and 60 by deleting part (b) and inserting "the Fc portion of an antibody." Support for this amendment can be found on page 7, lines 13-18 of the specification. Applicant has also amended claim 60 by inserting "having a condition characterized by selectin-mediated intercellular adhesion" so the language of claim 60 parallels that of claim 63.

Applicant presents new claims 72 and 73. Support for these claims can be found in Example 15.

These amendments do not add new matter.

II. Advisory Action

The Office contends that the response filed September 11, 2007, did not put the claims in condition for allowance. Advisory Action, p. 2. This assertion is made despite the fact that the September 11, 2007, Response was filed after two Examiner interviews held on July 17, 2007 and August 2, 2007, and the Response incorporated claim amendments specifically suggested by the Examiner. The Office concedes that "[t]he

non-P selectin ligand portion of the fusion protein was not discussed in the interview.”

Id. Nevertheless, the Office maintains the enablement rejection under 35 U.S.C. § 112, first paragraph. In addition, the Office asserts a new rejection under 35 U.S.C. § 112, second paragraph.

Applicant's responses to these rejections are set forth below.

III. Enablement Rejection under 35 U.S.C. § 112, first paragraph

The Office alleges that the claims are not enabled because “[e]ven though Example 15 teaches making some of the fusions with PSGL-1 fragments, e.g. 47.Fc, 47.AGP, 47.BMP2, and 47.IL11, the specification does not teach how to use such a broad genus of molecules.” Advisory Action, p. 2.

Applicant respectfully asserts that the claims are enabled. PSGL-1 binds to P-selectin, and thus could be used to target molecules to sites of P-selectin expression. Applicant respectfully asserts that the specification discloses how to make and use fusion proteins comprising PSGL-1 for such targeting. Nevertheless, solely to advance prosecution, Applicant has amended claims 58 and 60 by deleting “a non-P selectin ligand amino acid sequence chosen from an antibody, an arabinogalactan protein, a bone morphogenic protein, and a cytokine” and inserting “the Fc portion of an antibody.”

Applicant respectfully asserts that the amended claims are enabled. Example 10 A in the specification describes DNA constructs that can be used to make PSGL-1-IgG fusion proteins. That Example also describes how to use PCR to make DNA constructs that encode PSGL-1gG fusions, including primers sequences, PCR conditions, and disclosure on how to clone the PCR product. Examples 10 B and F provide methods for measuring the activity of the fusion proteins in cell-based binding assays. Example 13

describes how to use the claimed fusion proteins to inhibit binding of PSGL-1 to P-selectin. Accordingly, the skilled artisan could practice the invention without undue experimentation. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Applicant respectfully requests that the Office withdraw the rejection.

IV. Indefiniteness Rejection under 35 U.S.C. § 112, second paragraph

The Office rejects the claims under 35 U.S.C. § 112, second paragraph, as allegedly “indefinite for reciting ‘reducing leukocyte adherence.’” Advisory Action, p.2. According to the Office “it is unclear where leukocytes adhere to.” *Id.* The Office states that “[a]mending claims to ‘leukocyte adherence to the vascular endothelium’ or ‘leukocytes adhesion’ would overcome the rejection.” *Id.*

Applicant respectfully traverses. Applicant respectfully asserts that the scope of the claims would be understood by the skilled artisan. Nevertheless, solely to advance prosecution, Applicant has amended claims 58 and 60 by deleting “adherence” and inserting “adhesion to endothelial cells.” The invention relates to “inhibiting leukocyte adhesion to endothelial cells.” Specification, page 1, lines 17-18.

The Office also rejects claim 60 under 35 U.S.C. § 112, second paragraph. Advisory Action, p. 2. The Office alleges that “[t]he claim does not define what disease a ‘subject’ has.” *Id.* The Office states that “[a]mending the claim to recite ‘in a subject having a disease or condition characterized by selectin-mediated intercellular adhesion’ would overcome the rejection.” *Id.*

Applicants respectfully assert that the skilled artisan would understand the scope of claim 60 despite the express recitation of a “disease.” Claim 60 does not recite a disease. Nevertheless, solely to advance prosecution, Applicant has amended claim 60

by inserting “having a condition characterized by selectin-mediated intercellular adhesion” so that claim 60 parallels the language of claim 63.

Applicant respectfully requests that the Office withdraw the rejection.

V. New Claims

Applicant presents new claims 72 and 73. Independent claim 72 recites “reducing leukocyte adhesion to endothelial cells in a subject having a condition characterized by selectin-mediated intercellular adhesion,” the language suggested by the Office, and further recites a fusion protein comprising amino acid 42 to amino acid 313 of SEQ ID NO: 36, which is the first 47 amino acids of PSGL-1 (amino acids 42-88) and the Fc region of an antibody that is mutated at positions 234 and 237 of the native Fc sequence. See specification, Example 15.

Should the Office intend to reject the new claims based on the grounds for rejecting the previously presented claims, Applicant respectfully requests that the Office consider the following remarks.

New claims 72 and 73 are enabled. New claim 72 recites a fusion protein comprising the first 47 amino acids of PSGL-1 (amino acids 42-88) and the Fc region of an antibody that is mutated at positions 234 and 237 of the native Fc sequence. The specification describes how to make a DNA encoding such a protein in Example 15. The specification also discloses that a protein comprising amino acids 42-88 was able to inhibit binding of PSGL-1 to Cho cells that express P-selectin. See Figure 23. Accordingly, the specification describes how to make and use a fusion protein comprising amino acid 42 to amino acid 313 of SEQ ID NO: 36, and it would not constitute undue experimentation for the skilled artisan to practice the invention.

VI. Conclusion

In view of the foregoing remarks, Applicant respectfully requests withdrawal of these rejections and timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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